International Conference on Harmonization, E6: Good Clinical Practice (ICH, E6: GCP) Certificate Training Program

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Overview
Although various online GCP webinars are available (both free and with purchase), Regxia looked to create something unique that makes learning a fairly dry topic both fun and easy. The content of all GCP training programs are generally the same as they follow the ICH guidelines; however, we have extract the boring and inject some interest by not only adding to content, but with interactive audiovisual aspects.

The result was Learn@Regxia's online ICH GCP Certificate Training Program, designed to be completed by anyone involved with a clinical trial, including the primary investigator, physicians, nurses, students, staff and administrators. The training program provides an inclusive understanding of the GCP concepts as defined by the ICH, providing direct access to affiliated policies and guidance's of Health Canada, FDA and EMA through the Resource Bank.

Accessibility
One of the unique strengths of our online training program is the ability for the training to be completed entirely online -- anywhere, anytime. The training design team has used an intuitive and interactive system that provides personalized feedback for each user while recording their progress, allowing them to stop and start at any point in the program. This interactive system allows us to offer GCP training to everyone regardless of experience and previous exposure to the principles of GCP.

Certificate Program
In order to successfully complete each of the 8 learning sessions, and to be provided documented evidence that all the learning objectives have been completed, each user must complete quizzes at the end of each session which test the user's knowledge. This ensures that each user has gained a comprehensive understanding of the principles of GCP. Once the system records completion of all required sessions, a certificate will be provided which can be used to demonstrate educational/training compliance with regulatory requirements.

Time Commitment & CEUs
While the time require to complete the training varies by user due to the interactive nature of the program, the average time for completion is 5 hours. As such Learn@Regxia's ICH, E6: GCP Certificate Training Program is eligible for 5 educational contact hours with most professional certification bodies. Additionally, Learn@Regxia's ICH E6: GCP Certificate Training Program has been pre-approved by RAPS as eligible for up to 5 credits towards a participant's RAC recertification upon full completion.

The 8 sessions cover the following topics as specified in the ICH E6 guidelines:

GCP Session Title	**Description**
Introducing Good Clinical Practice	Session 1 delivers a pleasant introduction to GCP, enabling the learner to walk away with a strong beginning knowledge of the purpose and importance of GCP.
Institutional Review Board (IRB) & Independent Ethics Committee (IEC)	Session 2 works to create an understanding of the IRB and IEC's roles in clinical practice.

Investigator	Session 3 provides an understanding of the roles, responsibilities, and rights of the investigator and how they relate to the IRB/IEC, Sponsor and most importantly the trial subjects.
Sponsor	Session 4 delivers insight on the roles and responsibilities of the sponsor and how they too, relate to the other important bodies noted in GCP.
Monitoring	Session 5 aims to educate learners on how compliance with GCP is determined and what is required should non-compliance be determined.
Clinical Trial Design Protocol & Amendments	Session 6 presents information on what is expected to be included when designing a Protocol and the processes for its finalization and lifecycle management.
Investigator's Brochure	Session 7 provides an introduction to the Investigator's Brochure and then allows the learner to explore it more thoroughly.
Essential Documents	Session 8 conveys a timeline of the essential documents and outlines whose responsibility it is to complete, submit and update these documents.

Languages
Learn@Regxia's online ICH GCP Certificate Training Program is currently offered in English (text and audio), however a French (text and audio) version is in the planning stages of development.

User Experience
Each of the 8 sessions that make up Learn@Regxia's online training program benefit from engaging multi-media and interactive elements which work hand in hand with the rich audio and visual components to emphasize and cement the users comprehension of GCP.

User Testimonials
The current offering of Learn@Regxia's online ICH GCP Certificate Training Program has been adopted by CROs, pharmaceutical companies, and regulatory entities to replace their in house training and other international training providers as their preferred method for training and demonstrating GCP compliance.

> *"This webinar really solidified my previous knowledge of GCP with a greater understanding extending beyond the basic principles."* Learn@Regxia User, 01/13

> *"This was the third time I have taken a GCP training program and the first time I learned why it is so important."* Learn@Regxia User, 04/13

Planned Developments
In a continued effort to provide Canada's leading ICH GCP training program Learn@Regxia is continually listening to feedback and working on new developments to update our program to enhance the user learning experience.

Two featured updates currently in development are an online forum/discussion board for common issues experienced during clinical trials and potential solutions as posted by our GCP graduates and current registrants, and the offering of a condensed yearly recertification course for previous graduates of Learn@Regxia's online ICH GCP Certificate Training Program.